

### **REMARKS**

Undersigned counsel thanks Examiner Nguyen for extending the courtesy of a telephone interview held on June 28, 2005 to discuss the outstanding Office Action and the contents of this Response.

#### **Status of the claims**

Claims 1, 3, 4, 6-10, 12-34, 37, 39 and 40 were pending in this application; claims 10, 22, and 37 were withdrawn from consideration. Claims 1, 3, 4, 12, 16, 21 and 23 have been amended and claims 39-40 have been canceled without prejudice. As well, withdrawn claims 10, 22 and 37 have been canceled without prejudice to speed allowance of the pending claims. Upon entry of these amendments, claims 1, 3, 4, 6-9, 12-21 and 23-34 will be pending and under active consideration. Claims 1, 16, and 21-23 are independent.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

#### **Claim amendments**

Claims 1, 16, 21 and 23 have been amended to now recite that the donor liver tissues are obtained "between about 2 hours and 30 hours postmortem." The amendments find support throughout the specification and claims as filed, particularly at page 46, lines 11-12 and page 31, lines 12-15.

Applicants submit respectfully that the amendments presented herein are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

#### **Response to Amendment**

Applicants kindly thank the Examiner for withdrawing, in part, the claim rejection under 35 USC § 102(b) for want of novelty over Reid *et al.*; the rejection under 35 USC 102(e) for want of novelty over Faris; and the rejection under 35 USC 103(a) for obviousness over Reid *et al.* in view of Faris.

**Claim rejections under 35 U.S.C. §112, first paragraph**

Claims 1, 6-7, 16-21, 23-34 and 39-40 are newly rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Office Action alleges that (1) “Applicants did not contemplate obtaining any donor tissue greater than 30 hours post-mortem” and (2) “Applicants do [sic] not specifically contemplate to exclude obtaining any donor tissue less than about 2 hours postmortem.” Applicants respectfully traverse this rejection.

Without acquiescing to the propriety of the rejection and solely to advance the prosecution of the instant claims, Applicants first note that independent claims 1, 16, 21 and 23 have been amended to recite that the donor tissues are obtained “between about 2 hours and 30 hours postmortem.” Hence, at least with respect to point (1) above, Applicants respectfully submit that the rejection has been overcome and request that the rejection be withdrawn.

With respect to point (2), Applicants respectfully maintain that they are entitled to claim less than they initially and explicitly disclosed and need not present explicit support to the *exclusion* of any supported range *per se*. Indeed, “[w]ith respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider *inherently supported* by the discussion in the original disclosure. M.P.E.P. § 2163.05 III (emphasis added). In other words, Applicants need not provide evidence for the exclusion of any portion of a numerical range that is otherwise inherently supported.

Applicants respectfully submit that a time range to between about 2 hours and about 30 hours postmortem is more than adequately supported. As the Examiner notes, “livers [of the present invention are] obtained postmortem at different times but preferably within at least 24 hours, with a maximum of 30 hours.” Page 46, lines 11-12. *See also*, page 31, lines 12-15; page 41, lines 8-10; page 46 lines 1-12; and page 49, lines 3-7. What is more, specific examples of processing liver tissue at 2 hours and around 20 hours are provided in Figure 1 and Table 7, respectively. Taken together, Applicants respectfully submit that it is abundantly clear that Applicants contemplated practicing the invention at a time period that includes a range between

about 2 hours and about 30 hours postmortem, have provided substantial written support thereto and are entitled to claim same range.

Accordingly, Applicants respectfully submit that the 35 USC § 112, first paragraph, rejections have been overcome and respectfully request withdrawal of same claims.

**Claim rejections under 35 U.S.C. §112, second paragraph**

Claims 3-4, 8-9, 12-15, 21 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention for the reasons of record. In sum, the Examiner notes that claims 3-4, 8-9 and 12-15 depend from canceled claim 2 and that claims 21 and 23-34 recite method steps that do not relate to the preambles recited in the claims. Applicants respectfully traverse the rejection.

Applicants have amended claims 3-4, 8-9 and 12-15 to depend directly or indirectly from claim 1. As well, “providing” has been amended to “processing” in the preambles of independent claims 21 and 23.

On this basis, Applicants suggest respectfully that the § 112, second paragraph, rejections have been overcome, and Applicants request respectfully that same rejections be withdrawn.

**Claim rejections under 35 U.S.C. § 102**

Claims 39-40 stand rejected as allegedly being anticipated by PCT Application No. WO 95/13697 to Reid *et al.* (hereinafter, “Reid”), under 35 U.S.C. § 102(b). The Office Action alleges, in part, that “Applicants [have] failed to provide any objective evidence that distinguish the isolated hepatoblast cell populations prepared by the methods taught by Reid from any of the claimed compositions of the present invention.” Applicants traverse respectfully.

Without acquiescing to the propriety of the rejection and solely to advance prosecution of the instant application, Applicants have canceled claims 39 and 40 without prejudice to future prosecution in one or more continuation applications. Hence, Applicants submit respectfully that the rejections under 35 U.S.C. § 102(b) have been rendered moot and respectfully solicit withdrawal of same.

**CONCLUSION**

Applicants submit respectfully that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no additional fees due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



Gilberto M. Villacorta, PH.D.  
Registration No. 34,038  
Sunit Talapatra, PH.D.  
Registration No. 54,482

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Patent Administrator  
KATTEN MUCHIN ROSENMAN LLP  
525 West Monroe Street  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061